

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**APPLICATION NUMBER: 75-318**

**CHEMISTRY REVIEW(S)**

1. CHEMIST'S REVIEW NO. 4

2. ANDA #75-318

3. NAME AND ADDRESS OF APPLICANT

Invamed Inc.  
Attention: Mahendra Patel, Ph.D.  
2400 Rt. 130 North  
Dayton, NJ 08810

4. LEGAL BASIS FOR ANDA SUBMISSION

Generic version of Syntex Laboratories Inc's TICLID®  
(NDA 19-979). Patent certification and exclusivity statement  
are provided (Vol. 1.1, pp. 003-006).

U.S. Patent No. 4591592 expires May 27, 2003

5. SUPPLEMENT(s) N/A

6. ESTABLISHED NAME  
Ticlopidine Hydrochloride  
Tablets

7. PROPRIETARY NAME  
TICLID® Tablets

8. SUPPLEMENT(s) PROVIDE(s) FOR Original ANDA

9. AMENDMENTS AND OTHER DATES

Original Submission January 21, 1998  
Acknowledgement Letter February 20, 1998  
Major Amendment June 22, 1998  
Amendment Response July 2, 1998  
Fax Amendment 2/2/99  
Amendment Response 2/5/99  
Approvable letter 5/4/99  
Educational program letter 6/15/99  
Response to Educational program 6/28/99

10. PHARMACOLOGICAL CATEGORY

Inhibitor - Reduce the risk of thrombotic stroke (fatal or  
nonfatal) in patients who have experienced stroke precursors,  
and in patients who have had a completed thrombotic stroke.

11. Rx or OTC

12. RELATED DMF(s)

13. DOSAGE FORM  
**Tablets (Oral)**

14. STRENGTH  
**250 mg**

15. CHEMICAL NAME AND STRUCTURE

5-(o-Chlorobenzyl)-4,5,6,7-tetrahydrothieno-[3,2-c]  
pyridine hydrochloride

Formula:  $C_{14}H_{14}ClNS.HCl$

Molecular Weight: 300.25

*Drug substance and drug product are not official USP 23 items.*

16. RECORDS AND REPORTS None

17. COMMENTS

- a. All CMC deficiencies have been resolved satisfactorily.
- b. Labeling is **approvable** as of December 2, 1998 by C. Park.
- c. Bio is **satisfactory as of 4/27/98 by S Shrivasta..**
- d. DMF is now satisfactory as of 10/29/98.
- e. Methods validation for drug substance and drug product have been submitted to the Philadelphia District Laboratory; field has approved the methods as per W.Charles Becoat. See memo dated 2/26/99.
- f. Establishment evaluation submitted to compliance.
- g. Firm submitted proposal for implementation of educational program as requested by the Agency on 6/28/99 and found acceptable by M.Fanning on 7/12/99.

18. CONCLUSIONS AND RECOMMENDATIONS

**This application is tentatively APPROVED.**

19. REVIEWER: DATE COMPLETED:  
Karen A. Bernard, Ph.D. August 3, 1999

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Commercial/Confidential  
Information and are not  
releasable.

Chemistry, #38, 2/2/99